UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,543	02/17/2004	Moshe Flashner-Barak	1662/63202	3365

26646 7590 09/30/2009

KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
09/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,543	FLASHNER-BARAK ET AL.	
	Examiner	Art Unit	
	LESLIE A. ROYDS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-24* is/are pending in the application.

4a) Of the above claim(s) *7-19 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,20 and 22-24* is/are rejected.

7)☒ Claim(s) *5-6,22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 5-24 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed September 23, 2009 to enter the after-final papers dated August 31, 2009 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 1 and 5-24 are pending. Claims 7-19 and 21 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 1 and 20 are amended. Claims 1, 5-6, 20 and 22-24 are under examination.

Applicant's amendment to the instant claims to remove "ketoprofen" as the at least one poorly bioavailable drug to be used renders the previous prior art rejection directed to this particular specie of poorly bioavailable drug moot. Applicant is notified that examination has been expanded herein to the species of progesterone as the at least one poorly bioavailable drug for use in the instantly claimed composition.

Applicant's arguments, filed September 23, 2009, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Objection to the Claims

Claims 5-6 remain objected to as being dependent from a rejected base claim, but would be

allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Objections to the Claims (New Grounds of Rejection)

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, instant claim 20 is directed to specifying the degree of increase in the "average area under the blood or plasma concentration versus time curve". However, instant claim 22, which depends from instant claim 20, recites "the average AUC", which is broader than the "average area under the blood or plasma concentration versus time curve" of claim 20 and, thus, appears to fail to further limit the subject matter of instant claim 20. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the specification and claims as originally filed fail to provide adequate written description for the newly added limitation directed to wherein the average area under the blood or plasma

concentration versus time curve (AUC) of said composition is at least 5% more than the average AUC of a non-menthol containing formulation of the same drug (claim 20) or the limitation directed to wherein the average AUC of said composition is at least 15% more than the average AUC of a non-menthol containing formulation (claim 23).

Applicant discloses at p.4, l.25-31, "In one embodiment, the amount of menthol sufficient to increase the drug's bioavailability may be from about 20% to about 99% by weight, preferably, the menthol may be present in an amount of about 60% to about 95% by weight of the composition. Alternatively, the amount of menthol may be sufficient to increase the oral bioavailability of the drug by an increase of about 10% or more in the average area under the blood or plasma concentration versus time curve (AUC) when compared to the average AUC for a non-menthol containing composition of the drug."

Applicant additionally discloses at p.8, l.17-22, "The amount of menthol in the composition of the invention should be sufficient to improve the bioavailability of the poorly bioavailable drug. Typically, the amount of improvement should be at least about 5% of the average AUC as compared to the average AUC of a non-menthol containing formulation and preferably, the improvement is about 15%. One of ordinary skill in the art can easily determine with little or no experimentation the effective amount of menthol."

However, such disclosure of an increase of at least about 5% or 15% in the average area under the curve as compared to the average AUC for a non-menthol containing formulation fails to provide adequate written support to now claim an increase of at least about 5% or 15% for the average AUC of a specific concentration, i.e., *blood or plasma concentration*, as compared to the average AUC for a non-menthol containing formulation. This is a clear narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure because the original disclosure of an at least about 5% or 15% increase in the average AUC as compared to the average AUC for a non-menthol containing

formulation fails to provide written support to now claim that the at least about 5% or 15% increase occurs in the average area under the blood or plasma concentration versus time curve of the composition as compared to the average AUC of a non-menthol containing formulation of the same drug. It is clear, therefore, that Applicant was not in possession of the concept of an at least 5% (claim 20) or at least 15% (claim 23) increase in the average area under the blood or plasma concentration versus time curve compared to the average AUC of a non-menthol containing formulation, but rather was solely in possession of the concept of an at least 5% or 15% increase in the average AUC (i.e., not specific to a particular concentration *per se*) as compared to the average AUC for a non-menthol containing formulation.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the limitations directed to wherein the average area under the blood or plasma concentration versus time curve (AUC) of said composition is at least 5% more than the average AUC of a non-menthol containing formulation of the same drug (claim 20) or the limitation directed to wherein the average AUC of said composition is at least 15% more than the average AUC of a non-menthol containing formulation (claim 23).

Accordingly, the claim is considered to lack sufficient written description and is properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, there is insufficient antecedent basis for the limitations "the average area under the blood or plasma concentration versus time curve" or "the average AUC" as recited in instant claim 20, since the preceding text of the claim or the claim from which it depends fails to set forth any reference to "an average area under the blood or plasma concentration versus time curve" or "an average AUC" *per se*.

Furthermore, the phrase "the average AUC" as recited in instant claims 22-23 renders the claims indefinite because it is unclear whether it is intended to refer to the average area under the blood or plasma concentration versus time curve or the average AUC (i.e., AUC of *any* concentration, not limited to blood or plasma). In other words, the intended antecedent basis for the phrase "the average AUC" is not clearly set forth in the claims as presently written. As a result, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the scope of subject matter for which Applicant is presently seeking protection. Clarification is requested.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dugger III (U.S. Patent No. 6,110,486; 2000) in light of PDR for Herbal Medicines (p.628-631; 2004, already of record), cited to show a fact.

Dugger teaches buccal spray compositions for transmucosal administration of a pharmaceutically active compound soluble in a pharmacologically acceptable polar solvent comprising polar solvent in an amount of 75-99.8% by weight of the total composition; active compound in an amount of 1-20% by weight of the total composition; and also containing, a flavoring agent in an amount of 0.5-5% (col.2, l.5-14), as well as soft bite gelatin capsules for transmucosal administration of a pharmacologically active compound, at least partially soluble in a pharmacologically acceptable polar solvent comprising polar solvent in an amount of 40-99.8% by weight of the total composition, emulsifier in an amount of 0-20% by weight of the total composition; active compound in an amount of 0.03-35% and also comprising a flavoring agent in an amount of 0.05-60% by weight of the total composition (col.2, l.15-23). Dugger teaches that preferred flavoring agents include, *inter alia*, oil of peppermint (col.3, l.66-col.4, l.2) and the active compound may be, *inter alia*, progesterone (col.4, l.22-23). Exemplary formulations are disclosed, including a progesterone soft bite capsule as described in Example 9, which contains 85% polyethylene glycol, 7.89% glycerine, 5.0% lecithin, 1.11% progesterone and 1.0% oil of peppermint (Ex.9, col.8, l.24-50). Dugger teaches that the disclosed compositions provide the biologically active compound for rapid absorption through the oral mucosa (i.e., which is understood as a teaching that the composition is clearly "suitable for oral administration" as instantly claimed).

PDR for Herbal Medicines (p.628-631; 2004) is cited for its teaching that peppermint oil contains 35-45% menthol (col.2, para.4, p.628). Citation to this reference is made in accordance with MPEP §2131.01, which states that it is proper to rely upon a secondary reference for a rejection under 35 U.S.C. 102 provided that the additional reference is relied upon to demonstrate that a characteristic or property not disclosed by the primary reference is, in fact, inherent.

Accordingly, an amount of 1% peppermint oil as used in the particular exemplary composition would then contain 0.35-0.45% menthol by total weight of the composition. Though it is noted that the amount of menthol used in the composition of Dugger III (i.e., 0.35-0.45%) is outside "about 20%" as instantly claimed (instant claim 1) or "about 60%" as instantly claimed (instant claim 24), this teaching of 0.35-0.45% menthol by total weight of the composition is understood to meet Applicant's claimed amount of menthol of "about 20%" (claim 1) or "about 60%" (claim 24) because the term "about" as used in instant claim 1 or 24 permits some tolerance both above and below the recited endpoint absent an explicit definition of the degree of variation intended to be encompassed by the term. Where close prior art exists (such as, in this case, Dugger), the burden is on Applicant to establish that the term "about" as used in the instant claims is sufficiently clear to avoid such art. In the instant case, Applicant has failed to provide a definition of the term "about" in the instant specification, such that there is no indication or hint as to what amount of variation above or below the recited amount would constitute infringement of the instant claims. There is nothing in the specification, prosecution history or prior art that provides any indication as to what amount of variation is tolerated by the term "about". Absent such information, and further in view of what is actually disclosed by Dugger (i.e., 0.35-0.45% menthol by total weight of the composition), this teaching of Dugger is understood to meet Applicant's claimed amount of "about 20%" (claim 1) or "about 60%" (claim 24), absent factual evidence to the contrary, and further absent any clear indication in the specification or claims that an amount of 0.35-0.45% would not be encompassed by the variation in and around the endpoint of "about 20" (claim 1) or "about 60%" (claim 24).

Regarding Applicant's limitations directed to (1) wherein the average area under the blood or plasma concentration versus time curve (AUC) of said composition is at least 5% more than the average AUC of a non-menthol containing formulation of the same drug (claim 20), (2) wherein the average AUC of said composition is at least 10% more than the average AUC of a non-menthol containing formulation (claim 22) or (3) wherein the average AUC of said composition is at least 15% more than the average

AUC of a non-menthol containing formulation (claim 23), the pharmaceutical composition of Dugger comprises the identical active agents in an identical physical structure (e.g., a composition suitable for oral administration) in identical amounts to that instantly claimed. Therefore, the composition of Dugger must necessarily possess the same AUC characteristics (as defined in instant claims 20 and 22-23) as that presently claimed whether recognized by the patentee or nor because products of identical chemical composition cannot exert mutually exclusive properties when prepared or used in the same manner under the same circumstances. In other words, if the prior art teaches the identical chemical or physical structure of the composition (i.e., same active agents, same physical structure, same amounts, etc.), the properties that Applicant discloses and/or claims must necessarily be present. See MPEP §2112.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that the subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 592, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is, in fact, inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, though Dugger may not expressly teach the average AUC of the disclosed composition versus the average AUC of the disclosed composition without the menthol component, the prior art to Dugger contains the same active agents as that presently claimed in the same physical structure and in the same amounts, and, therefore, the resultant AUC properties must also be the

same, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, Dugger does not possess these same claimed characteristics.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dugger III (U.S. Patent No. 6,110,486; 2000) in view of PDR for Herbal Medicines (p.628-631; 2004, already of record).

Dugger teaches buccal spray compositions for transmucosal administration of a pharmaceutically active compound soluble in a pharmacologically acceptable polar solvent comprising polar solvent in an amount of 75-99.8% by weight of the total composition; active compound in an amount of 1-20% by weight of the total composition; and also containing, a flavoring agent in an amount of 0.5-5% (col.2, l.5-14), as well as soft bite gelatin capsules for transmucosal administration of a pharmacologically active compound, at least partially soluble in a pharmacologically acceptable polar solvent comprising polar

solvent in an amount of 40-99.8% by weight of the total composition, emulsifier in an amount of 0-20% by weight of the total composition; active compound in an amount of 0.03-35% and also comprising a flavoring agent in an amount of 0.05-60% by weight of the total composition (col.2, l.15-23). Dugger teaches that preferred flavoring agents include, *inter alia*, oil of peppermint (col.3, l.66-col.4, l.2) and the active compound may be, *inter alia*, progesterone (col.4, l.22-23). Exemplary formulations are disclosed, including a progesterone soft bite capsule as described in Example 9, which contains 85% polyethylene glycol, 7.89% glycerine, 5.0% lecithin, 1.11% progesterone and 1.0% oil of peppermint (Ex.9, col.8, l.24-50), and further teaches that the flavoring agent may be included in an amount of 0.05-5% (col.8, l.30-35). Dugger teaches that the disclosed compositions provide the biologically active compound for rapid absorption through the oral mucosa (i.e., which is understood as a teaching that the composition is clearly "suitable for oral administration" as instantly claimed).

PDR for Herbal Medicines (p.628-631; 2004) is cited for its teaching that peppermint oil contains 35-45% menthol (col.2, para.4, p.628). Citation to this reference is made in accordance with MPEP §2131.01, which states that it is proper to rely upon a secondary reference for a rejection under 35 U.S.C. 102 provided that the additional reference is relied upon to demonstrate that a characteristic or property not disclosed by the primary reference is, in fact, inherent.

Note that the exemplary progesterone formulation contains 1% peppermint oil by weight of the total composition or suggests that the flavoring agent (which, in this exemplary formulation, is peppermint oil) may be used in an amount of 0.05-5% for this disclosed example (Ex.9, col.8, l.25-50), Dugger explicitly teaches that the flavoring agent, including, *inter alia*, peppermint oil, is used in an amount of 0.05-60% by weight of the total composition when the composition is in the form of a soft bite gelatin capsule comprising polar solvent, emulsifier and the active compound (see, e.g., p.2, l.15-22). Such disclosure is an unambiguous teaching that the amount of the flavoring agent of this progesterone soft bite capsule may be varied within the disclosed parameters of 0.05-60% by weight of the total

composition and still arrive at a product contemplated and within the scope of the invention disclosed by Dugger. This is because it is evident that the progesterone soft bite capsule of Example 9 (discussed *supra*) is employing a narrower range of flavoring agent of the broader range disclosed for the purposes of providing an exemplary formulation, but the fact that Dugger discloses a broader range of possible amounts of flavoring agent that may be used (i.e., in this case, peppermint oil) supports the interpretation that Dugger contemplated the substantial interchangeability of the amount of flavoring agent while still preserving the advantageous properties of the invention such that the amounts of the components (i.e., in this particular case, the amount of flavoring agent) may be varied therein the disclosed parameters and still form a preparation within the scope of the invention, absent factual evidence to the contrary.

Further note that, if Dugger was to provide a progesterone formulation such as that described in Example 9 but with a greater amount of the flavoring agent used therein (i.e., peppermint oil), such as 0.05-60% as disclosed at col.2, l.15-22, such a range of peppermint oil would then contain between 0.0175% menthol [(0.05/100) x (35/100) x 100 = 0.0175%] and 27% menthol [(60/100) x (45/100) x 100 = 27%], which clearly overlaps with the amounts instantly claimed in, e.g., instant claim 1. Note that, again, though the amount of menthol suggested by the compositions of Dugger III (i.e., 0.0175-27%) is outside "about 60%" as instantly claimed (instant claim 24), this teaching of 27% menthol by total weight of the composition is understood to meet Applicant's claimed amount of menthol of "about 60%" (claim 24) because the term "about" as used in instant claim 24 permits some tolerance both above and below the recited endpoint absent an explicit definition of the degree of variation intended to be encompassed by the term. Where close prior art exists (such as, in this case, Dugger), the burden is on Applicant to establish that the term "about" as used in the instant claims is sufficiently clear to avoid such art. In the instant case, Applicant has failed to provide a definition of the term "about" in the instant specification, such that there is no indication or hint as to what amount of variation above or below the recited amount would constitute infringement of the instant claims. There is nothing in the specification, prosecution history or prior art

that provides any indication as to what amount of variation is tolerated by the term "about". Absent such information, and further in view of what is actually disclosed by Dugger (i.e., 0.0175-27% menthol by total weight of the composition), this teaching of Dugger is understood to meet Applicant's claimed amount of "about 60%" (claim 24), absent factual evidence to the contrary, and further absent any clear indication in the specification or claims that an amount of 0.0175-27% would not be encompassed by the variation in and around the endpoint of "about 60%" (claim 24).

Regarding Applicant's limitations directed to (1) wherein the average area under the blood or plasma concentration versus time curve (AUC) of said composition is at least 5% more than the average AUC of a non-menthol containing formulation of the same drug (claim 20), (2) wherein the average AUC of said composition is at least 10% more than the average AUC of a non-menthol containing formulation (claim 22) or (3) wherein the average AUC of said composition is at least 15% more than the average AUC of a non-menthol containing formulation (claim 23), the pharmaceutical composition of Dugger comprises the identical active agents in an identical physical structure (e.g., a composition suitable for oral administration) in identical amounts to that instantly claimed. Therefore, the composition of Dugger must necessarily possess the same AUC characteristics (as defined in instant claims 20 and 22-23) as that presently claimed whether recognized by the patentee or nor because products of identical chemical composition cannot exert mutually exclusive properties when prepared or used in the same manner under the same circumstances. In other words, if the prior art teaches the identical chemical or physical structure of the composition (i.e., same active agents, same physical structure, same amounts, etc.), the properties that Applicant discloses and/or claims must necessarily be present. See MPEP §2112.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation, the burden is shifted to the Applicants to "prove that the subject matter to be shown in the prior art does not possess

the characteristic relied on" (205 USPQ 592, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is, in fact, inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, though Dugger may not expressly teach the average AUC of the disclosed composition versus the average AUC of the disclosed composition without the menthol component, the prior art to Dugger contains the same active agents as that presently claimed in the same physical structure and in the same amounts, and, therefore, the resultant AUC properties must also be the same, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, Dugger does not possess these same claimed characteristics.

Conclusion

Rejection of claims 1, 20 and 22-24 is proper.

Claims 5-6 are objected to for depending from a rejected base claim.

Claims 7-19 and 21 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

September 25, 2009